

DOCKET NO.: MPCI-0033
Application No.: 09/928,467
Office Action Dated: October 25, 2004

PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-82, 85, 87-106, 109, 110, 113-116, 122, 125-127, and 132 are cancelled and claims 83-84, 86, 107-108, 111, 117-120, 123-124, 128-129 and 133-134 are amended herein as follows:

1-82. **(Canceled).**

83. **(Currently Amended)** The method of claim [[106]] 112 wherein the stabilizer is ethanol, acetone, ~~glycerin, propylene, glycol, polyethylene glycol,~~ isopropyl alcohol, or methanol, ~~or polysorbates.~~

84. **(Currently Amended)** The method of claim [[106]] 112 wherein the stabilizer is ethanol.

85. **(Canceled).**

86. **(Currently Amended)** The method of claim [[106]] 112 wherein the anion of a mineral acid is chloride ions.

87-106. **(Canceled).**

107. **(Currently Amended)** The method of claim [[106]] 112 wherein the mineral acid is present in an amount to provide from 20 ppm to about 55 ppm of the anion of the mineral acid, based on the weight of gabapentin.

108. **(Currently Amended)** The method of claim [[106]] 112 wherein the mineral acid is present in an amount to provide from 20 ppm to about 40 ppm of the anion of the mineral acid, based on the weight of gabapentin.

109-110. **(Canceled).**

111. **(Currently Amended)** The method of claim [[106]] 112 wherein the dry dosage form further comprises at least one pharmaceutically acceptable adjuvant.

112. **(Previously Presented)** A method of preparing stable pharmaceutical formulations in dry dosage form comprising the steps of:

dissolving a mineral acid in a stabilizer,

wetting gabapentin with the mineral acid solution, and

removing a substantial portion of the stabilizer to form gabapentin crystals comprising gabapentin molecules and a mineral acid present in an amount to provide at least 20 ppm of an anion of the mineral acid, based on the weight of gabapentin, said mineral acid dispersed throughout each gabapentin crystal, wherein said formulation contains less than 1% by weight of the lactam degradation product of gabapentin after being stored for 3 months at 40 degrees Centigrade and 75 % relative humidity.

113 -116. **(Canceled).**

117. **(Currently Amended)** The method of claim [[113]] 121 wherein the dry dosage form further comprises at least one pharmaceutically acceptable adjuvant.

118. **(Currently Amended)** The method of claim [[113]] 121 wherein the stabilizer is ethanol, acetone, ~~glycerin, propylene glycol, polyethylene glycol,~~ isopropyl alcohol, or methanol, ~~or polysorbates.~~

119. **(Currently Amended)** The method of claim [[113]] 121 wherein the stabilizer is ethanol.

120. **(Currently Amended)** The method of claim [[113]] 121 wherein the anion of a mineral acid is chloride ions.

121. **(Previously Presented)** A method of preparing stable pharmaceutical formulations in dry dosage form comprising the steps of:

dissolving a mineral acid in a stabilizer,

wetting a cyclic amino acid which is susceptible to formation of a lactam with the mineral acid solution, and

removing a substantial part of the stabilizer to form crystals of the cyclic amino acid, said crystals comprising the cyclic amino acid and a mineral acid present in an amount to provide at least 20 ppm of an anion of the mineral acid, based on the weight of the cyclic amino acid, said mineral acid dispersed throughout each crystal of the cyclic amino

acid, wherein said formulation contains less than 1% by weight of the lactam after being stored for 3 months at 40 degrees Centigrade and 75 % relative humidity.

122. **(Canceled).**

123. **(Currently Amended)** The method of claim [[122]] 121 wherein the mineral acid is present in an amount to provide from 20 ppm to about 55 ppm of the anion of the mineral acid, based on the weight of gabapentin.

124. **(Currently Amended)** The method of claim [[122]] 121 wherein the mineral acid is present in an amount to provide from 20 ppm to about 40 ppm of the anion of the mineral acid, based on the weight of gabapentin.

125-127. **(Canceled).**

128. **(Currently Amended)** The method of claim [[106]] 112 wherein the stabilizer is a volatile [[an]] organic liquid with a dielectric constant below 60.

129. **(Currently Amended)** The method of claim [[113]] 121 wherein the stabilizer is a volatile [[an]] organic liquid with a dielectric constant below 60.

130. **(Previously Presented)** The method of claim 112 further comprising the step of:
dry-mixing the gabapentin crystals with a pharmaceutically acceptable adjuvant.

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131. **(Previously Presented)** The method of claim 121 further comprising the step of:
dry-mixing the cyclic amino acid crystals with a pharmaceutically acceptable
adjuvant.

132. **(Canceled).**

133. **(Currently Amended)** The method of claim ~~[[106]]~~ 112 wherein the mineral acid in
each crystal of gabapentin is uniformly dispersed.

134. **(Currently Amended)** The method of claim ~~[[113]]~~ 121 wherein the mineral acid in
each crystal of gabapentin is uniformly dispersed.